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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/473,270	12/27/1999	VICTOR SKLADNEV	3415/29	9784

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NEW YORK, NY 100160601

EXAMINER

LU, TOM Y

ART UNIT	PAPER NUMBER
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2621

DATE MAILED: 06/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/473,270

Applicant(s)

SKLADNEV ET AL.

Examiner

Tom Y Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 30-60, 66 and 67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-29 and 61-65 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-29 and 61-65 in Paper No. 7 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-22 and 61-63 are rejected under 35 U.S.C. 112, 2nd Paragraph as being vague and indefinite and under 35 U.S.C. 112 1st Paragraph as lacking adequate support in the disclosure.

- a. Claim 1 recites the limitation "all cones positioning their respective windows at the same distance from said imaging device" in lines 6-7. There is insufficient antecedent basis for this limitation in the claim. The drawing figure 2 shows there is an amount of distance between the outer window 147 and inner window 133. Therefore, the examiner would like to know how it is possible to have *same distance* from the imaging device.
- b. Claims 2-20 are rejected as being dependent upon Claim 1.
- c. Claim 2 recites the limitation "one cone has multiple colours around its transparent window permanently" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Applicant in the specification, page 24, lines 32-34, discloses "throughout this application, a reference-white material is used. However, this is only the

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preferred colour material. Any reference material of known stable colour can be used.”

Applicant states there is only one colour placed on the transparent window. In addition, the examiner finds no further explanation with regarding to “has multiple colours around its transparent window”.

- d. Claim 3 is rejected as being dependent upon Claim 2.
- e. Claim 21 is rejected to for the same reason given in Claim 1.
- f. Claim 22 is rejected as being dependent upon Claim 21.
- g. Claim 61 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. “a plurality of reference targets of known colours on an outer surface” critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Examiner fails to find any explanation with regarding to “a plurality of reference targets of known colours on an outer surface” in the specification.
- h. Claim 62 is rejected to as being dependent upon Claim 61.
- i. Claim 63 is rejected to for the same reason given in Claim 61.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

- 3. Claims 1, 7-8 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Binder (U.S. Patent No. 6,032,071).

- a. Referring to Claim 1, Binder discloses a hand-held case (Binder at column 12, line 8, discloses a compact device 100 which is a hand-held unit as shown in

figure 5), a source of light inside the case for directing light toward the front of the case (Binder at column 13, lines 10-12, discloses “four 4.5 V halogen miniature incandescent bulbs 510 are positioned in four uniformly distributed recesses in this holder”), an imaging device in the case for generating imaging signals from light derived from said area of skin (Binder at column 12, lines 28-31, discloses “a microvideo camera 400 with a lens section 410 mounted in the lens housing 411 is arranged centrally and axially in the housing 200 as an imaging-recording and observation device”), and at least two cones attachable to the front of said case each having a transparent window for bearing against an area of skin (Binder at column 12, line 10, discloses a front housing section 201 bearing a front plate 210 made of transparent material, which corresponds to one of the claimed “cones”. Binder at column 12, line 28, discloses a lens housing section 410 includes a polarization foil 610, which is transparent as well), each of said cones serving a different function and having properties different from the other cones (Binder at column 14, lines 48-55, discloses the front housing section 201 serves as a spacer unit and thus maintains the correct focus to the light – sensitive element or sensor 400, the glass plate 210 seals off the device keeps the object to be recorded, namely the skin 150, flat and prevents any foreign bodies from entering the device. Binder at column 12, lines 53-56, discloses camera lens housing 411 with projecting section fits over the housing, which protects the microcamera 400), but all cones positioning their respective windows at the same distance from said imaging device (see paragraph 2.a above, Binder discloses the

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front housing section and lens housing section are on same central axis as shown on figure 5).

- b. Referring to Claim 7, Binder discloses wherein at least one of said cones is adapted to permit the imaging of a lesion, and another of said cones is adapted to permit the imaging of a relatively substantial portion of the patient (Binder discloses the front housing section 201 is adapted to permit the imaging of a lesion, and lens housing 411 is adapted to permit the imaging of a relatively substantial portion of the patient).
- c. Referring to Claim 8, Binder discloses wherein said source of light includes a plurality of individual light sources facing the front of the case with a diffuser in front of each of said sources (Binder at column 12, line 42, discloses a light diffuser).
- d. Referring to Claim 18, Binder discloses wherein said source of light includes a plurality of individual light sources sufficiently separated that the reflections of each individual light source from the patient's skin or the surface of said window lie outside the field of view of said imaging device (Binder at figure 6 shows the separation of 4 light sources, and at column 13, lines 48-54, discloses the reflection of light from the skin to the imaging device).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binder in view of Gutkowicz-Krusin (U.S. Patent No. 6,208,749 B1). All the arguments and applicability in paragraph 3.a are incorporated herein.

- a. Referring to Claim 2, Binder does not disclose wherein at least one cone has multiple colours around its transparent window permanently in the field of view of said imaging device to aid in the calibration of said imaging device. Gutkowicz-Krusin at column 8, lines 1-3, discloses a plurality of narrowband filters, each one corresponding to a different spectral wavelength band, are mounted on a filter wheel 29 as shown in figure 2, such filter wheel provides multiple colors. At the time the invention was made it would have been obvious to a person of ordinary skill in the art to have multiple colors around its transparent window. One of ordinary skill in the art would have been motivated to do this because such color filtering provides information on lighting and image system conditions at the time of image capture.
- b. Referring to Claim 3, Gutkowicz-Krusin discloses wherein colours are on the outside of said window so that the colours are imaged in the same plane and under the same optical conditions as the patient's skin when the window bears against the patient's skin (Column 8, lines 1-3, figure 2 shows the color filter wheel is outside the lens 14).
- c. Referring to Claim 4, Gutkowicz-Krusin discloses having a non-transparent planar section at the front thereof whose colour is a known reproducible reference

colour (Gutkowicz-Krusin discloses the color filter wheel is a non-transparent planar section).

5. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binder in view of Van Heuvelen (U.S. Patent NO. 4,704,029).

a. As applied to Claim 9, which is representative of Claim 10, Binder discloses wherein said plurality of individual light sources are arranged in a plane (see figure 6). Binder does not disclose each of said light sources being slightly inclined to a central axis of the hand-held unit. Van Heuvelen discloses that. At the time, the invention was made, it would have been obvious to a person of ordinary skill in the art to do this because by making each of the light sources being slightly inclined to a central axis, the angle of incidence of the light is selected to be slightly less than the critical angle for total internal reflection. By having total internal reflection, it improves the light intensity for the imaging signal quality taken by the camera.

6. Claims 19-22 and 64-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binder.

b. With regarding to Claim 21, the only difference between Claim 21 and Claim 1 is Claim 21 calls for additional limitation of "each having a transparent window of same thickness". Binder at column 14, lines 48-55, discloses the glass plate 210 seals off the device keeps the object to be recorded, namely the skin 150, flat and prevents any foreign bodies from entering the device. Binder at column 12, lines 53-56, discloses camera lens housing 411 with projecting section fits over the

housing, which inherently protects the microcamera 400. Therefore, it really does not alter the scope of the invention with regarding to the thickness of the windows. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have two windows with same thickness. One of ordinary skill in the art would have been motivated to do this because it is a matter of design choice, and it is not critical to the invention.

- c. With regarding to Claim 19, the limitation is addressed in Claim 21 above.
- d. As applied to Claim 20, which is representative of Claim 22, it would be obvious for a person of ordinary skill in the art to make the glass thickness be 5 millimeters.
- e. With regarding to Claim 64, the only difference between Claim 21 and Claim 64 is Claim 64 calls for the thickness to be at least 5 millimeters; it would be obvious for a person of ordinary skill in the art to make the glass thickness be 5 millimeters because it is simply a matter of design choice.
- f. Referring to Claim 65, Binder discloses wherein said transparent window has side edges that are absorptive and non-radiating (Binder at column 14, lines 51-53, discloses the glass plate 210 seals off the device and keeps the object to be recorded, namely the skin 150, flat and prevents any foreign bodies from entering the device, which implies the edge of the plate is absorptive and non-radiating from the plurality of light sources).

7. Claims 13-17, 23, 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binder in view of Muraki et al (U.S. Patent No. 5,463,497).

- a. Referring to Claim 23, Binder discloses a hand-held case having a transparent window for bearing against said area of skin, and a source of light inside the case for directing light toward the front of the case, said source of light including a plurality of light output ports facing the front of the case and arranged in a plane. However, Binder does not disclose with pairs of intensity distribution from said output ports being spatially separated such that they overlap at their half-intensity levels so that the resulting summation of their intensities has a flat central region. Muraki at column 4, lines 20-26, discloses when these light beams LB1 and LB2 are inputted to the light receiving surface of the optical integrator 22 and partially overlap one upon another, the combined light has sectional intensity distribution which, as shown in figure 2C, is symmetrical with respect to the optical axis and, additionally, it is substantially uniform. A flat central region is substantially uniform. And the light sources are overlap at their half-intensity levels as shown in figure 2C. At the time the invention was made it would have been obvious to a person of ordinary skill in the art to implement Muraki's technique in Binder's system. One of ordinary skill in the art would have been motivated to do this because Binder at column 12, lines 35-47, teaches to have a light diffuser and polarization device to achieve uniform light intensity for better imaging quality during the skin examination.
- b. With regarding to Claim 13, the limitation is addressed in Claim 23.
- c. As applied to Claim 14, which is representative of Claim 16, Binder at figure 6 shows four individual light sources are arranged at the corners.

- d. Referring to Claim 15, Muraki discloses wherein pairs of intensity distributions from said individual light sources are spatially separated such that they satisfy the Raleigh criterion for the separation of two Gaussian pulses (Muraki at column 15-17, discloses the laser light from the laser 11 has a sectional intensity distribution, which is in the form of a Gaussian distribution. And later Muraki at column 4, lines 20-25, discloses two light beams LB1 and LB2 are combined to have a sectional intensity distribution as shown in figure 3C, which two Gaussian pulses partially overlap each other, and satisfies the Raleigh criterion as the claim calls for).
 - e. Referring to Claim 17, Binder discloses wherein said individual light sources are sufficiently separated that the reflection of each individual light source from the patient's skin or the surface of said window lie outside the field of view of said imaging device (Binder at figure 6 shows the separation of 4 light sources, and at column 13, lines 48-54, discloses the reflection of light from the skin to the imaging device).
 - f. With regarding to Claim 27, the limitation is addressed in Paragraph 3.d above.
 - g. With regarding to Claim 28, the limitation is addressed in Paragraph 7.c above.
 - h. With regarding to Claim 29, the limitation is addressed in 7.e above.
8. Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binder and Muraki as applied to claim 23 above, and further in view of Van Heuvelen.
- a. With regarding to Claim 24, the limitation is address in Paragraph 5.a above.
 - b. With regarding to Claim 25, the limitation is addressed in Paragraph 6.c above.

- c. With regarding to Claim 26, the limitation is addressed in Paragraph 7.e above.

9. Claims 11/9, 11/10, 12/9 and 12/10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binder and Van Heuvelen as applied to claim 9 or 10 above, and further in view of Muraki.

- a. With regarding to Claim 11/9, the limitation is addressed in Paragraph 7.a above.
- b. With regarding to Claim 11/10, the rejection is same as Claim 11/9 above.
- c. With regarding to Claim 12/9, all the arguments and applicability in Claim 23 is incorporated herein, Binder does not discloses wherein pairs of intensity distributions from said individual light sources are spatially separated such that they satisfy the Raleigh criterion for the separation of two Gaussian pulses. Muraki at column 15-17, discloses the laser light from the laser 11 has a sectional intensity distribution which is in the form of a Gaussian distribution. And later Muraki at column 4, lines 20-25, discloses two light beams LB1 and LB2 are combined to have a sectional intensity distribution as shown in figure 3C, which two Gaussian pulses partially overlap each other, and satisfies the Raleigh criterion as the claim calls for. The motivation for combining Binder and Muraki is same as Claim 23.

- d. With regarding to Claim 12/10, the rejection is same as Claim 12/9.

10. Claims 5-6 and 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binder in view of Takemura et al (U.S. Patent No. 5,232,781).

- a. Referring to Claim 61, Binder discloses a cone for a hand-held unit that facilitates the imaging of an area of patient's skin, said hand-held unit having a case, a

source of light inside the case for directing light toward the front of the case, and an imaging device for generating an imaging signal from light derived from said area of skin, said cone having a transparent window at the front. Binder does not disclose a plurality of reference targets of known colours (Applicant in the specification, page 24, lines 32-34, discloses only one reference colour material is used every time, therefore, examiner only needs to address one colour to be coated on the glass) on an outer surface that bears against the skin of a patient, said cone being attachable to the front of said case and having a removable reference material thereon. Takemura at column 33, lines 34-41, discloses coating organic colorant on glass, and such colorant is removable. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to coat a colour layer on the window glass. One of ordinary skill in the art would have been motivated to do this because Binder at column 14, lines 54-55, teaches for hygienic reasons, the glass plate 210 is designed to be replaceable. Therefore, it would be reasonable for an ordinary skill in the art to replace the coated layer instead of the glass plate for economical reasons as well as current medical ethics. In addition, Takemura at column 34, line 36, teaches using the colorant coating on the glass eliminates see-through visibility, and provides glare proof. In another words, it reduces light reflection, which Binder at column 13, line 52, teaches the illumination device would like to avoid.

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- b. With regarding to Claim 5, the limitation of "one cone is adapted to have a removable layer of a known reproducible colour attached thereto" is addressed in Claim 61.
- c. Referring to Claim 62, which is representative of Claim 6, Binder discloses wherein said reference material is on said window such that upon removal it cannot be re-used (Binder discloses for hygienic reasons, it is desired to have the glass plate replaceable, in this case, it is the colorant coating layer).
- d. With regarding to Claim 63, all the limitations are addressed in Paragraph 10.a above.

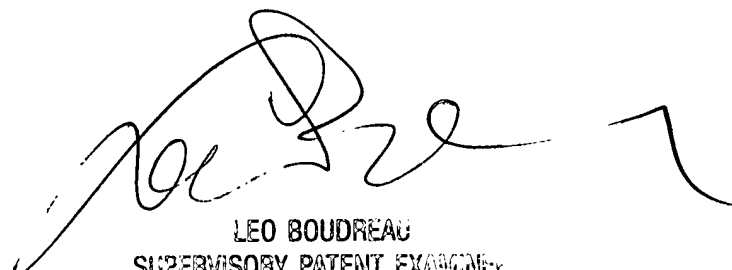
Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tom Y Lu whose telephone number is (703) 306-4057. The examiner can normally be reached on 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo H Boudreau can be reached on (703) 305-4706. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9314 for regular communications and (703) 872-9314 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3900.

Tom Y. LU
May 31, 2003


LEO BOUDREAU
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